

Introduction

Transplantation is the procedure involving the removal of a bodily organ or tissue from one person, and the insertion of that organ or tissue into another person to replace a damaged organ or tissue.

Definition of Terms:

Allograft – transplant from one individual to another (synonymous with homograft)

Hereotopic graft – transplant placed in a site different than the organ's normal location

Orthotopic graft – transplant placed in its normal anatomical site

Syngeneic graft (isograft) – transplant between identical twins

Xenograft – transplant between different species

Organ transplantation is now well established as an effective treatment for selected patients with end-stage organ failure. Transplantation of the kidney, liver, pancreas, heart, and lungs are all routine procedures, and transplantation of the small intestine is becoming more widely practiced. Currently, transplant activity is limited only by the shortage of cadaveric organs.

The following policy contains the minimal criteria for solid organ transplants. Additional justification may be required at the discretion of the Division of Medical Assistance Hospital Consultant staff.

1.0 Definition of the Procedure

Lung transplantation is surgery to replace one or both diseased lungs with healthy lungs from a human donor. Lung transplantation has become a viable option for carefully selected patients with end stage pulmonary disease.

2.0 Eligible Recipients

2.1 General Provisions

Medicaid eligible individuals with a need for this specialized treatment confirmed by a licensed physician are eligible as long as they meet individual eligibility requirements. Medicaid recipients may have service restrictions due to their eligibility category, which would make them ineligible for this service.

2.2 Special Provisions

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that provides recipients under the age of 21 with medically necessary health care to correct or ameliorate a defect, physical or mental illness or a condition identified through a screening examination. While there is no requirement that the service, product or procedure be included in the State Medicaid Plan, it must be listed in the federal law at 42 U.S.C. § 1396d(a). Service limitations on scope, amount or frequency described in this coverage policy do not apply if the product, service or procedure is medically necessary.

The Division of Medical Assistance's policy instructions pertaining to EPSDT are available online at <http://www.dhhs.state.nc.us/dma/prov.htm>.

3.0 When the Procedure is Covered

Each recipient's condition is evaluated on an individual basis. There may be other conditions that are indications for coverage.

The N.C. Medicaid program covers lung transplantation for patients with end-stage lung disease of any etiology who meet the following criteria:

3.1 Primary Pulmonary Disease

1. emphysema, including alpha-1 antitrypsin deficiency emphysema
2. obliterative bronchiolitis
3. bronchiectasis, cystic fibrosis, and other disorders of ciliary function
4. interstitial lung disease, including: idiopathic pulmonary fibrosis, sarcoidosis limited to the lungs, lymphangioleiomyomatosis, eosinophilic granuloma, drug induced pulmonary fibrosis, and occupational lung disease with fibrosis
5. primary pulmonary hypertension
6. secondary pulmonary hypertension
7. bronchopulmonary dysplasia

3.2 Congenital Heart Disease (Eisenmenger's Defect or Complex)

3.3 Pediatric

1. pulmonary vascular disease
2. bronchiolitis obliterans
3. bronchopulmonary dysplasia
4. cystic fibrosis

3.4 Disease Specific Criteria

3.4.1 Cystic Fibrosis

1. cycling intravenous antibiotic therapy
2. non-invasive nocturnal mechanical ventilation
3. frequent hospitalizations
4. worsening arterial-alveolar gradient
5. FEV1 < 30%

3.4.2 Emphysema and Alpha-1 Antitrypsin Deficiency Emphysema

1. hospitalizations with hypercapnia
2. reduced serum albumin
3. decreased body mass index
4. increasing oxygen needs
5. cor pulmonale
6. FEV1 < 30%

3.4.3 Eisenmenger's

1. signs of right ventricular failure
2. ascites
3. hepatomegaly
4. hemoptysis
5. deterioration in functional capacity
6. worsening hypoxemia

3.4.4 Sarcoidosis

1. presence of cor pulmonale
2. pulmonary hypertension
3. FEV1 < 50% or total lung capacity < 70%

3.4.5 Pulmonary Fibrosis

1. hypoxia
2. hypercapnia
3. FEV1 < 70%

3.4.6 Pulmonary Hypertension

1. NYHA III failing conventional vasodilators (calcium channel blockers)
2. parental vasodilator therapy

4.0 When the Procedure is Not Covered

Lung transplants are not covered when the medical necessity criteria listed in **Section 3.0** are not met. Each recipient's condition is evaluated on an individual basis. There may be other conditions that are indications for non-coverage.

The N.C. Medicaid program does not cover lung transplantation when one of the following conditions exists (not all inclusive).

4.1 Absolute

1. advanced age (generally over 65) for a single transplant, and advanced age (generally over 60) for a bilateral transplant
2. irreversible renal and/or hepatic dysfunction
3. HIV infection
4. active Hepatitis B or C
5. steroid therapy 20 mg or more/day
6. smoking/tobacco use – must be abstinent for a minimum of one year
7. history of or active substance abuse – must have documentation of substance abuse program completion plus six months of negative sequential random drug screens

Note: To satisfy the requirement for sequential testing as designated in this policy, the Division of Medical Assistance (DMA) must receive a series of test (alcohol and drug) results spanning a minimum six-month period, allowing no fewer than a three-week interval and no more than six-week interval between each test during the given time period. A complete clinical packet for prior approval must include at least one documented test performed within one month of the date of request to be considered.
8. pulmonary malignancy (history of non-pulmonary malignancy will be reviewed on a case-by-case basis)
9. current patient and/or caretaker non-compliance that would make compliance with a disciplined medical regime improbable
10. psychosocial history that would limit ability to comply with medical care pre and post transplant
11. single lung transplant is contraindicated in patients with cystic fibrosis, chronic bronchitis, bronchiectasis and other chronic pulmonary infections

4.2 Relative

1. patients with multi-system disease (i.e., scleroderma, systemic lupus erythematosus, or sarcoidosis must be screened carefully)
2. systemic steroid therapy exceeding 10 mg per day
3. infection with pan resistant Burkholderia cepacia
4. obesity
5. recent or unresolved pneumonia or pulmonary infection
6. immobility
7. laser ablation of emphysematous pulmonary bullae and lung volume reduction surgery

4.3 Donors

Living donor expenses **are not applicable** for lung transplants.

5.0 Requirements for and Limitations on Coverage

All applicable N.C. Medicaid policies and procedures must be followed in addition to the ones listed in this procedure.

All lung transplantations must be prior approved by DMA.

6.0 Providers Eligible to Bill for the Procedure

Physicians enrolled in the N.C. Medicaid program who perform this procedure may bill for this service.

7.0 Additional Requirements

FDA approved procedures, products, and devices for implantation must be utilized for lung transplantation.

Implants, products, and devices must be used in accordance with all FDA requirements current at the time of surgery.

A statement signed by the surgeon certifying all FDA requirements for the implants, products, and devices must be retained in the recipient's medical record and made available for review upon request.

8.0 Policy Implementation/Revision Information

Original Effective Date: January 1, 1990

Revision Information:

Date	Section Revised	Change
7/1/05	Entire Policy	Policy was updated to include coverage criteria effective with approved date of State Plan amendment 4/1/05.
9/1/05	Section 2.2	The special provision related to EPSDT was revised.
12/1/05	Section 2.2	The web address for DMA's EDPST policy instructions was added to this section.
2/1/06	Section 3.4.4	Pulmonary infiltrates without hilar adenopathy and non-pulmonary features were deleted as coverage criteria for sarcoidosis; the criteria for total lung capacity was revised to <70%.

Attachment A Claims Related Information

Reimbursement requires compliance with all Medicaid guidelines including obtaining appropriate referrals for recipients enrolled in the Medicaid Managed Care programs.

A. Claim Type

1. Providers bill professional services on the CMS-1500 claim form.
2. Hospitals bill for services on the UB-92 claim form.

B. Diagnosis Codes that Support Medical Necessity

Providers must bill the ICD-9-CM diagnosis code to the highest level of specificity that supports medical necessity.

C. Procedure Codes

Codes that are covered include:

32851	32852	32853	32854
-------	-------	-------	-------

D. Providers must bill their usual and customary charges.